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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,804	11/01/2000	Christine C. Dykstra	5470-263	2773

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	13

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,804	DYKSTRA ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,49,58 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-25* is/are allowed.

6)☒ Claim(s) *49,58 and 59* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 49, 58, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boykin et al., 6,127,554.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Feb. 6, 2003.

Claims 26-48 and 50-57 are cancelled without prejudice. No new claims are added. Claims 1-25, 49, 58, 59 are currently pending.

Applicant's Supplemental Information Disclosure Statement received Feb. 19, 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

The previous claim objections set forth in paragraph 4 of the office action mailed Nov. 6, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claims rejection under 35 USC 103(a) set forth in paragraphs 5-7 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Nov. 6, 2002 with the following additional comment:

It is Applicant's position that the prior art to Boykin et al. does not disclose or fairly suggest the claimed pharmaceutical composition. Specifically, Applicant contends that the mere

occurrence of an embodiment of Formula IV of the present invention in the Boykin et al. patent does not render the claimed formulations obvious. Furthermore, Applicant argues that the compounds disclosed in Boykin et al. are useful in compositions for the treatment of *Pneumocystis carinii* pneumonia in mammals, whereas the claimed invention is a pharmaceutical formulation for treating infectious bursal disease virus (IBDV) in an avian subject.

Moreover, Applicant argues that the Examiner's reliance on In re Susi and Merck and Co. v. Biocraft Laboratories does not serve to render the present claims unpatentable. The Susi and Merck cases are distinguishable from the instant invention in that these cases dealt with claims directed to novel compounds which were deemed to be particular species of compounds in which a generic encompassing the species had been previously claimed and patented in the prior art. However, the claims of the application are directed to pharmaceutical formulations with a specific use, i.e. the treatment of IBDV. Therefore, it is not possible for the claims of the instant application to be a species of a genus described in the Boykin et al. patent.

Additionally, concerning the Examiner's remarks regarding the intended use of the claimed formulations, Applicant argues that the In re Casey and In re Otto cases are inapplicable to the claimed invention because the MPEP limits the use of these cases to machinery which works upon and article or material in its intended use (see MPEP 2115). The claims, however, are directed to pharmaceutical compositions. Finally, Applicant asserts that the Examiner relied upon impermissible hindsight in concluding that the claimed compositions would be capable of treating IBDV.

Said arguments have been considered but are not found to be persuasive.

The examiner respectfully maintains that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). While the Casey and Otto cases may only apply to machinery, it remains a well settled principle that the intended use of a composition is not patentably significant. Please see In re Hack, 114 USPQ 161 (CCPA 1957). Please also see In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, cannot impart patentability to claims to the known composition."); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) (" [M]ere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957) ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); and In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent

upon an old product based solely upon discovery of a new use for such product"). In view of the above, the Examiner respectfully submits that Applicant's argument concerning the specific use of the composition to treat IBDV is unpersuasive. The claimed pharmaceutical composition is obvious over the Boykin et al. patent. Therefore, the new intended use of the composition, i.e. to treat IBDV, cannot render the claimed composition patentable.

Additionally, Applicant's argument that the Merck and Susi cases are distinguished from the claimed invention because they relate to claims of novel compounds and not pharmaceutical compositions having a specific use of treating IBDV in avian subjects is noted. However, the Examiner respectfully submits that the cases are relevant to the instant application. These cases dealt with compounds. The claims of the instant application recite the use of compounds in a pharmaceutical composition. It is the compound which confers the therapeutic activity. The claimed pharmaceutical composition serves to put compounds in a form suitable for administration to a patient.

Therefore, the Examiner respectfully maintains that the claims of the instant application recite a pharmaceutical composition containing a specific species and a more limited subgenus of compounds that are disclosed in the Boykin et al. patent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any of the species taught by the Boykin reference, including those of the claims, because one of ordinary skill in the art would have the reasonable expectation that any of the species of the genus would have similar properties and thus the same use as the genus as a whole. Moreover, it has been held that a prior

art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. Please see In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971) followed by the Federal Circuit in Merck and Co. v. Biocraft Laboratories, 87 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Finally, the Examiner respectfully submits that the disclosed pharmaceutical compositions of the compounds embraced by Formula I would be capable of treating IBDV. Please see the Boykin et al. patent col. 3, lines 19-34, where Boykin et al. disclose effective dosage amounts which overlap significantly with Applicant's effective dosage amounts (please see the specification page 15, line 30 to page 16, line 4).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim Objections

3. Claims 1 and 49 are objected to because of the following informalities: in claims 1 and 49, the term --and-- should be added after "Formula (III)" and before the compound represented

by "Formula (IV)". Such an amendment would result in proper Markush language, i.e. --selected from the group consisting of...and--. Appropriate correction is required.

Conclusion

4. Applicant's amendment necessitated the new claim objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

June 17, 2003

MARIANNE C. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600